DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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May 11, 2015

Nobel Biocare AB
c/o Ms. Ji Eun Hwang
Nobel Biocare USA, LLC
22715 Savi Ranch Parkway
Yorba Linda, CA 92887

Re: K142260
Trade/Device Name: NobelActive®
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: April 7, 2015
Received: April 8, 2015

Dear Ms. Hwang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tina Kiang -S

for Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142260

Device Name
NobelActive(R)

Indications for Use *(Describe)*

NobelActive® implants are endosseous implants intended to be surgically placed in the upper or lower jaw bone for anchoring or supporting tooth replacements to restore patient esthetics and chewing function.

NobelActive® implants are indicated for single or multiple unit restorations in splinted or non-splinted applications. This can be achieved by a 2-stage or 1-stage surgical technique in combination with immediate, early or delayed loading protocols, recognizing sufficient primary stability and appropriate occlusal loading for the selected technique.

NobelActive® 3.0 implants are intended to replace a lateral incisor in the maxilla and/or a central or lateral incisor in the mandible.

NobelActive® 3.0 implants are indicated for single unit restorations only.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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A.4. 510(k) Summary K142260

I. SUBMITTER

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Contact Name: Ji Eun Hwang, Sr. Regulatory Affairs Manager
Phone: 714-282-4800 x5030
Fax: 714-998-9348

Date Prepared: March 20, 2015

II. DEVICE

Proprietary Name: NobelActive®
Common or Usual Name: Endosseous Dental Implant
Classification Name: Endosseous Dental Implant (21 CFR 872.3640)
Regulatory Class: II
Product Code: DZE, NHA

III. PREDICATE DEVICE

Nobel Biocare – NobelActive® Internal Connection Implant (K071370 Primary Predicate)

Nobel Biocare – NobelActive® 8.5 mm & 18.0 mm (K083205 Reference Predicate)

Nobel Biocare – NobelActive® 3.0 (K102436 Reference Predicate)

Nobel Biocare – NobelActive® Wide Platform (WP) (K133731 Reference Predicate)

IV. DEVICE DESCRIPTION

Nobel Biocare's NobelActive® implants are threaded, root-form dental implants intended for use in the upper and/or lower jaw to support prosthetic devices, such as artificial teeth, in order to restore patient esthetics and chewing function to partially or fully

edentulous patients. They are intended for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

The NobelActive® implants are available in diameters 3.0, 3.5, 4.3, 5.0, and 5.5 mm. They are available in lengths between 6.5 mm to 18 mm depending upon implant diameter.

This premarket notification is being submitted to support labeling changes. No additional implants are being introduced.

V. INDICATIONS FOR USE

NobelActive® implants are endosseous implants intended to be surgically placed in the upper or lower jaw bone for anchoring or supporting tooth replacements to restore patient esthetics and chewing function.

NobelActive® implants are indicated for single or multiple unit restorations in splinted or non-splinted applications. This can be achieved by a 2-stage or 1-stage surgical technique in combination with immediate, early or delayed loading protocols, recognizing sufficient primary stability and appropriate occlusal loading for the selected technique.

NobelActive® 3.0 implants are intended to replace a lateral incisor in the maxilla and/or a central or lateral incisor in the mandible.

NobelActive® 3.0 implants are indicated for single unit restorations only.

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VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

CHARACTERISTIC		CANDIDATE	PRIMARY PREDICATE	REFERENCE PREDICATE	REFERENCE PREDICATE	REFERENCE PREDICATE
		NobelActive®	NobelActive® Internal Connection Implant (K071370)	NobelActive® 8.5 mm & 18.0 mm (K083205)	NobelActive® 3.0 (K102436)	NobelActive® Wide Platform (WP) (K133731)
Features	Thread Design	**Double lead thread Reverse cutting flutes**	Double lead thread Reverse cutting flutes	Double lead thread Reverse cutting flutes	Double lead thread Reverse cutting flutes	Double lead thread Reverse cutting flutes
	Implant Body Design	**Expanding Taper Drilling blades on apex**	Expanding Taper Drilling blades on apex	Expanding Taper Drilling blades on apex	Expanding Taper Drilling blades on apex	Expanding Taper Drilling blades on apex
	Implant Length	**7.0, 8.5, 10.0, 11.5, 13.0, 15.0, 18.0 mm**	10.0, 11.5, 13.0 mm	8.5, 18.0 mm	10.0, 11.5, 13.0, 15.0 mm	7.0, 8.5, 10.0, 11.5, 13.0 mm
	Implant Width	**3.0, 3.5, 4.3, 5.0, 5.5 mm**	3.5, 4.3, 5.0 mm	3.5, 4.3, 5.0 mm	3.0 mm	5.5 mm
	Connection Type	**Internal Hex**	Internal Hex	Internal Hex	Internal Hex	Internal Hex
	Device Material	**CP Titanium**	CP Titanium	CP Titanium	CP Titanium	CP Titanium
	Surface	**TiUnite**	TiUnite	TiUnite	TiUnite	TiUnite
Intended Use/ Principles of Operation		**Nobel Biocare's NobelActive® implants are threaded, root-form dental implants intended for use in the upper and/or lower jaw to support prosthetic devices, such as artificial teeth, in order to restore patient esthetics and chewing function to partially or fully edentulous patients.**	Nobel Biocare's NobelActive® implants are threaded, root-form dental implants intended for use in the upper and/or lower jaw to support prosthetic devices, such as artificial teeth, in order to restore patient esthetics and chewing function to partially or fully edentulous patients.	Nobel Biocare's NobelActive® implants are threaded, root-form dental implants intended for use in the upper and/or lower jaw to support prosthetic devices, such as artificial teeth, in order to restore patient esthetics and chewing function to partially or fully edentulous patients.	Nobel Biocare's NobelActive® implants are threaded, root-form dental implants intended for use in the upper and/or lower jaw to support prosthetic devices, such as artificial teeth, in order to restore patient esthetics and chewing function to partially or fully edentulous patients.	Nobel Biocare's NobelActive® implants are threaded, root-form dental implants intended for use in the upper and/or lower jaw to support prosthetic devices, such as artificial teeth, in order to restore patient esthetics and chewing function to partially or fully edentulous patients.

Comparison of Indications for Use

Candidate: NobelActive®
NobelActive® implants are endosseous implants intended to be surgically placed in the upper or lower jaw bone for anchoring or supporting tooth replacements to restore patient esthetics and chewing function.

NobelActive® implants are indicated for single or multiple unit restorations in splinted or non-splinted applications. This can be achieved by a 2-stage or 1-stage surgical technique in combination with immediate, early or delayed loading protocols, recognizing sufficient primary stability and appropriate occlusal loading for the selected technique.

NobelActive® 3.0 implants are intended to replace a lateral incisor in the maxilla and/or a central or lateral incisor in the mandible.

NobelActive® 3.0 implants are indicated for single unit restorations only.

Primary Predicate: NobelActive® Internal Connection Implant (K071370) Nobel Biocare's NobelActive® implants are endosseous implants intended to be surgically placed in the bone of the upper and/or lower jaw arches to provide support for prosthetic devices, such as an artificial tooth, in order to restore patient esthetics and chewing function. Nobel Biocare's NobelActive® implants are indicated for single or multiple unit restorations in splinted or non-splinted applications. Nobel Biocare's NobelActive® implants may be placed immediately and put into immediate function provided that initial stability requirements detailed in the manual are satisfied.

Predicate: NobelActive 8.5 mm & 18.0 mm (K083205)
Nobel Biocare's NobelActive® implants are endosseous implants intended to be surgically placed in the bone of the upper and/or lower jaw arches to provide support for prosthetic devices, such as an artificial tooth, in order to restore patient esthetics and chewing function. Nobel Biocare's NobelActive® implants are indicated for single or multiple unit restorations in splinted or non-splinted applications. Nobel Biocare's NobelActive® implants may be placed immediately and put into immediate function provided that initial stability requirements detailed in the manual are satisfied.

Predicate: NobelActive 3.0 (K102436)
The NobelActive® 3.0mm implant is indicated for use in the treatment of missing maxillary lateral incisors or the mandibular central and lateral incisions to support prosthetic devices, such as artificial teeth, in order to restore chewing function in partially edentulous patients. The NobelActive® 3.0 implants may be put into immediate function provided that stability requirements detailed in the manual are satisfied.

Predicate: NobelActive Wide Platform (WP) (K133731)
Nobel Biocare's NobelActive® implants are endosseous implants intended to be surgically placed in the bone of the upper and/or lower jaw arches to provide support for

prosthetic devices, such as an artificial tooth, in order to restore patient esthetics and chewing function. Nobel Biocare's NobelActive® implants are indicated for single or multiple unit restorations in splinted or non-splinted applications. Nobel Biocare's NobelActive® implants are intended for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

VII. PERFORMANCE DATA

Non-Clinical Data

Two bench studies were conducted to demonstrate performance of the subject device.

The first study validated the recommended drilling protocols by placing implants in various bone surrogates. Results support that the implant (4.3x13 mm) was fully seated in a Type 3 bone surrogate at 55 N cm when using a 2.8/3.2 as the last drill. The implant was fully seated in a Type 4 bone surrogate at 45 N cm when using a 2.4/2.8 as the last drill.

The second study evaluated primary stability and micro-motion with different implant geometries and simulated bone densities (i.e. 30 pcf – Type II to III, and 20 pcf – Type III to IV per Lekholm and Zarb). After placement, the implants were subjected to sinusoidal loading intended to simulate immediate mechanical loading for approximately 3 months. NobelActive® implants exhibited significantly less micro-motion than the comparator devices in both bone surrogates ($p \leq 0.05$). The study also demonstrated that the NobelActive® implants showed higher mechanical resistance to cyclic loads in a clinically relevant loading scenario.

Clinical Data

Several studies support the substantial equivalence of the subject device.

In two separate clinical studies, NobelActive® implants were placed in healed sites and in extraction sites. The classification of bone quality was done per Lekholm and Zarb by the treating surgeon according to standard methods including imaging, presurgical investigation of the site/patient, and tactile sensation. The study protocols used a 1-stage surgical procedure (i.e. no submerged healing) in combination with an immediate loading protocol. Insertion procedures were performed according to the individual needs of the site using the recommended drill protocols in the Instructions for Use.

A total of 199 NobelActive® implants were placed in healed sites (7 – Quality Type 4, 86 - Quality Type 3, 88 - Quality Type 2, and 18 - Quality Type 1). The mean insertion torque achieved with NobelActive® implants was 51.1 (SD 19.5) N cm in all bone qualities and 46.15 (SD 17.5) N cm in predominantly cancellous bone (Quality 3 and 4 according to Lekholm and Zarb). The study had a control group (NobelReplace), which achieved a lower mean, i.e. 41.3 (SD 11.6) N cm in all bone qualities. In cancellous

bone, the control group (NobelReplace) also achieved a lower insertion torque of 39.29 (SD 8.55) N cm compared to the values achieved with NobelActive®.

137 NobelActive® implants were placed in extraction sites (2 – Quality Type 4, 70 – Quality Type 3, 63 – Quality Type 2, and 2 – Quality Type 1). The mean insertion torque achieved with NobelActive® implants was 47.21 (SD 11.4) N cm in all bone qualities and 48.00 (SD 11.45) N cm in predominantly cancellous bone (Quality 3 and 4 according to Lekholm and Zarb).

Between these two studies, a total of 164 NobelActive® were placed in predominantly cancellous bone (Type III and IV) in both extraction (72 implants) and healed (93 implants) sites, of which 5 implants had failed; meaning that 97% of the implants were successful after 3 years. In healed sites, 96.8% of the implants were successful and in extraction sites 97.2% were successful. Those numbers are well in the range of usually reported values for other implants in all types of bone.

In a separate implant handling study, four (4) clinicians placed 88 implants (26 in soft bone (Type 4), 47 in medium bone (Type 3/2), and 13 in dense bone (Type 1; 2 missing values). Data from this study showed that clinicians underprepared sites in soft bone and could reach high insertion torques, most often in the range required for immediate loading (lowest reported range 30 – 40 N cm).

Irinakis and Wiebe (2009) conducted a prospective study on NobelActive® implants. Within a 13 month period, a total of 140 implants were placed in the maxilla and mandible in both extraction and grafted sites. Of these sites, 24 were classified by the investigator as being soft quality bone. The mean insertion torque achieved was 47.9 N cm, which is the exact same mean as seen in medium bone, and is slightly lower than in dense bone. The implants were successful as there was only a 2.1% failure rate (of all implants placed) during the observation period.

Demanet *et al* (2011) reported 3 year results of 466 implants placed in all jaw regions, of which 58 implants were in the posterior maxilla, a usually very soft bone quality. The total survival rate was 99.1% and for the posterior region it was 98.3%, leading to the assumption that the implant performed well in all jaw bone regions.

VII. CONCLUSION

The differences in intended use between the subject and predicate devices (primary and reference devices) are the identification of the available surgical protocols and the inclusion of all previously cleared lengths and widths of the Nobel Active family of products. These changes do not alter the intended use of the device, which is to be surgically placed in the upper or lower jaw bone for anchoring or supporting tooth replacements to restore patient esthetics and chewing function. The changes instead encompass and harmonize the intended use for all NobelActive family products.

Furthermore, the subject devices have the same design characteristics, implant to-abutment connections (3.0, NP, RP, WP), materials (CP Ti), surface treatment (TiUnite), internal hex connection, packaging and sterilization process as the identified primary and reference predicate devices. Additionally, the subject device encompasses all previously cleared dimensions of the primary and reference predicate devices.
Based on the information provided above and within this submission, the subject devices are substantially equivalent to the predicate devices.